35. Effect of a Panothenic Acid–Deficient Diet on Monamine Oxidase (MAO) and Deoxyribonucleic Acid (DNA) in Rat Liver (J. Pharmaceutical Sciences, Jan. 1967).
36. Diffuse Reflectance Studies of Solid-Solid Interactions.
II. Interaction of Metallic and Non-metallic Adjuvants With Anthracene. Prednisone and Hydrochlorothiazide (J. Pharmaceutical Sciences, Oct. 1966).
37. Diffuse Reflectance Studies of Solid-Solid Interactions.
III. Interaction Studies of Oxytetracycline with Metallic and Non-metallic Adjuvants (J. Pharmaceutical Sciences, Oct. 1966).
38. Comparative Hydrolytic Rates of N-Substituted 6-Amino-thiouracils (J. Pharmaceutical Sciences, May 1967).

PAPERS TO BE SUBMITTED

1. Kinetics of Meperidine Degration.
2. Synthesis and Antifungal Activity of Some Halogenated Diphenolic—In print.
3. Kinetics of Glutethimide Decomposition—In print.
4. The Effect of Schardinger Dextrin on the Hydrolytic Rate of O, M and P-ethylaminobenzoate.

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STATEMENT OF DR. JOHN L. LACH

I am Dr. John L. Lach, Professor of Pharmacy in the College of Pharmacy, University of Iowa. I have previously served as an Assistant Professor and Associate of Pharmacy at that institution, and also served as an instructor in pharmacy at the University of Wisconsin after securing my Ph.D. degree there. Well known to the Chairman of this Subcommittee is the fact that the University of Wisconsin is considered one of the leading research centers in the world in the field of physical pharmacy.

For the past several years my special field of interest in pharmaceutical research has been the application of physical-chemical principles to pharmaceutical systems involving stability studies, complex formation, formulation and analytical techniques, and more recently drug excipient interactions in dosage forms.

I appreciate the privilege that has been extended to me to submit my views, for your consideration, on certain aspects of the important questions before this committee.

For some time physicians, pharmacists and the general public have been subjected to considerable discussion of a widely proposed answer to the rising costs of federally financed health care programs—namely, the prescribing of generic drugs as one means for holding down the expenditure of tax funds for the care of the elderly and welfare recipients. These discussions have not only appeared in professional and trade journals but also in the lay press. A good deal of it has taken place on the floor of Congress.

In the time I have today, it is not my purpose to try to examine the entire generic issue. Rather, I will limit my discussion to the subject of "generic equivalency," about which you have heard much and doubtless will hear more during the course of these hearings.

With all the sincerity I can muster, I would like to ask you to delve deeply into this matter for so much depends on it in reaching sound and objective conclusions in the overall controversy.

Before there can be a realization of the full implications of what is being proposed, for example, I believe there must be a much broader understanding than now exists as to what goes into the manufacture of a quality dosage form or pharmaceutical product.

There are the raw materials, of course, but there is more. Quality and therapeutic effectiveness must be built into the drug product by the manufacturer through each step in the formulation process. The public, members of the health team, and, yes, members of Congress, must be educated to the fact that manufacture of a quality drug product or dosage form involves many aspects other than a minimum knowledge of how to make a tablet, a suspension, an injectable or solution. An awareness and recognition and an understanding of these other factors is absolutely essential before one can objectively examine the term "generic equivalent." It is indeed unfortunate that this term has been so frequently used, not only by people in government but by physicians and pharmacists—unfortunate in the sense that these individuals have applied this generic term to dosage forms—one which was never intended.